PSJ17 Exh 46

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

THIS DOCUMENT APPLIES TO ALL CASES

No. 17-MD-2804

Hon. Dan A. Polster

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HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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FRIDAY, FEBRUARY 1, 2019

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Videotaped Deposition of STACEY BECKHARDT, held at the Law Offices of Skikos Crawford Skikos & Joseph, One Sansome Street, Suite 2830, San Francisco, California, beginning at 9:40 a.m., before Sandra Bunch VanderPol, FAPR, RMR, CRR, CALIFORNIA CSR #3032

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(Appearances continued on next page)

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information about Actiq and Fentora to the media; correct?

A. That's correct.

Q. And sometimes you would be involved in what types of messages you would give the media about these products; correct?

A. That's correct.

Q. And, for example, sometimes you would be involved with giving the media messages about Actiq and Fentora related to what types of products they are; correct?

A. That's correct.

Q. And sometimes you would give the media information about Actiq and Fentora about what they could be used for; correct?

A. That is correct.

Q. And when we say "media," we're not talking only about television, for example, radio, for example, but we're also talking about the print media?

A. That's correct.

Q. So, for example, the Wall Street Journal or other AP types of newspapers, for example; correct?

A. That's correct.

Q. So a lot of your job, it looked like, or a big part of your job, included messaging with the media about these two narcotic opioid drugs; correct?

A. That's a portion of my job.

MR. JAMES: Misstates her testimony.

BY MR. CARTMELL:

Q. You can restate your answer, please.

A. It was a portion of my job.

Q. Now, the other things, it looks like from your documents, that you were involved with and you mentioned on your LinkedIn page is that you partnered with industry groups, patient groups, professional societies and key opinion leaders; correct?

A. That's correct.

Q. What do you mean when you partnered with those groups? What do you mean by that?

A. We developed -- we spoke about breakthrough pain, what breakthrough pain was. There was lack of awareness of the condition. So both breakthrough pain, breakthrough cancer pain, and what -- what the needs of those patient populations were.

Q. When you say you partnered with

industry groups, give the jury some idea of what an industry group in the pain community might be.

A. The primary industry group was a coalition called the Pain Care Coalition. It involved industry groups, patient advocacy organizations, and professional societies.

Q. So would that pain coalition, as you called it, involve multiple pharmaceutical companies in the industry?

A. That's correct.

Q. And so sometimes you would work with those industry groups on the messaging that would be given about, for example, opioids in general?

A. That's not correct.

Q. Let me ask you this, then. Would you sometimes be involved with that coalition related to, for example, as you mentioned, breakthrough pain and the messaging related to breakthrough pain?

A. To increase the understanding of breakthrough pain, yes.

Q. And then you also mentioned that part of your job in public relations, and as it related to these opioid narcotics, had to do with your partnering with patient groups; right?

A. That's correct.

Q. Now, one of the things, I think, that you would do is actually from time to time be involved with providing some type of pamphlets or brochures, or things like that, actually to patients?

A. That's not correct.

Q. Okay. Let me re-ask it. Actually, strike that.

When you would partner with patient groups about these opioid narcotic medications, what would you do typically? Tell the jury.

MR. JAMES: Misstates her testimony.

THE WITNESS: Can you clarify that question, please?

BY MR. CARTMELL:

Q. One of the things you would do during your time at Cephalon and during the time that you were in the Public Relations Department working with Fentora and Actiq, the opioid narcotics, was you would work with patient groups, for example; is that true?

A. That's true.

Q. Give the jury an example of what you mean when you say "a patient group."

A. A patient group are organizations that represent the interests of people with a

C2 opioid.

MR. CARTMELL: I'm going to object and move to strike that. That's not my question.

Q. It's apparent from reviewing this document, this Risk Management Program, that the FDA required of Cephalon -- that the FDA was concerned about the risks of abuse or misuse and diversion and addiction related to Actiq; correct?

MR. JAMES: Objection.

THE WITNESS: Yes, they were concerned. But the reason they were concerned was because it was a C2 opioid.

BY MR. CARTMELL:

Q. Okay. And it's true, from looking at this document, that the FDA was requiring Cephalon, your company, to make sure that it was sending the appropriate messages to doctors, physicians, and pharmacists about the safety of this product; correct?

MR. JAMES: Objection.

THE WITNESS: Yes. And we did.

BY MR. CARTMELL:

Q. And it's true, is it not, from this Risk Management Program, that the FDA required -- that one of those messages that was required of

Cephalon to be sent to these physicians, patients, and pharmacists was that Actiq should be used solely by cancer patients with breakthrough pain and who are opioid tolerant; correct?

MR. JAMES: Objection.

THE WITNESS: Those are the messages that were required and that were given.

BY MR. CARTMELL:

Q. Okay. We will talk about whether or not they were given. Okay?

Now, is it true that you were involved in some of these vehicles that this Risk Management Program is talking about, as far as delivering messages?

A. I was not responsible for delivering messages directly to health-care providers who were prescribers or dispensing of the medication.

Q. What about delivering --

A. In that context.

Q. I'm sorry.

What about delivering messages to patient groups or industry groups or professional societies, were you involved in --

A. Yes.

Q. -- delivering those messages?

You were; correct?

A. I was involved in giving those messages as they related to management of breakthrough cancer pain and breakthrough pain.

Q. And would you agree with me that it was Cephalon's obligation to provide information through the groups that were listed that was consistent with the goals of the Risk Management Program?

MR. JAMES: Objection.

THE WITNESS: What groups -- to which -- what groups are you referring to? What section are you --

BY MR. CARTMELL:

Q. You will recall that the Risk Management Program we just went through talked about giving messages to physicians and pharmacists and patients; correct?

A. Yes.

Q. And in certain circumstances giving these messages to professional societies, for example; correct?

A. In certain circumstances, yes.

Q. And would you agree with me that it was Cephalon's obligation to provide those messages

to those groups that were consistent with the goals of the Risk Management Program?

MR. JAMES: Objection.

THE WITNESS: Yes.

(Exhibit No. 8 was marked.)

MR. CARTMELL: I'm handing you what's been marked as Exhibit 8.

Q. Ms. Beckhardt, we just looked at the Risk Management Program for Actiq. And I will represent to you that this is the Risk Management Program, sometimes referred to as the RiskMAP, for Cephalon's other opioid narcotic, Fentora.

Do you see that?

A. Yes.

Q. And, again, I take it that this is another Risk Management Program that you became familiar with during your time working at Cephalon; is that fair?

A. Yes.

Q. And you needed to become familiar with the Risk Management Program because of your involvement with providing messages related to Fentora; correct?

A. Messages related to the approval of the product and its usage and data related to it to

A. Yes.

Q. A couple paragraphs down it says:

(Reading) The FDA approved Actiq for use only in opioid-tolerant cancer patients. Between 2001 and 2006, Cephalon allegedly promoted the drugs for noncancer patients to use for such maladies as migraine, sickle cell pain crises, injuries and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use with patients who were not opioid-tolerant (end of reading).

Do you see that?

A. I see what it says, yes.

Q. And we just looked at the marketing plans and strategy and tactics that the company was using in 2002 and 2003. And some of the things in those plans are included here, including sickle cell therapy strategy to expand into that use; correct?

A. That is correct.

Q. Do you know whether or not, in fact, this was -- that strategy of off-label marketing was actually engaged in from 2001 to 2006, or was that

something that if it was, you didn't know about?

MR. JAMES: Objection.

THE WITNESS: I was aware there was increased usage of our product in other -- other than cancer.

BY MR. CARTMELL:

Q. Okay. Did you at the time suspect that part of that large increase in off-label usage may be the result of the sales team or the marketing strategy put in place?

MR. JAMES: Objection.

THE WITNESS: I had some suspicions, yes.

BY MR. CARTMELL:

Q. Did you talk to anybody about that, any management, while you were there?

A. Yes.

Q. Who did you talk to about that?

A. My supervisor.

Q. Who was your supervisor at the time?

A. Cheryl Williams.

Q. And what were you told in response to your concerns?

A. I don't recall. But she did not have oversight over the marketing strategy in any shape or form.

Q. Did you ever talk to Mr. Pyfer and tell him that you had concerns that he was instituting a strategy and tactics of off-label promotion?

A. I don't recall.

Q. You may have, you just don't remember?

A. I don't recall.

Q. In retrospect, now knowing that you had suspicions and concerns about the off-label promotion and marketing at the time at Cephalon, do you wish you had done more to try to stop it?

MR. JAMES: Objection.

THE WITNESS: I don't know how to answer that question. I don't know the answer.

BY MR. CARTMELL:

Q. Have you thought about that?

A. No, I have not thought about that.

Q. It states below:

(Reading) Cephalon undertook its off-label promotional practices via a variety of techniques, such as training its sales force to disregard restrictions of the FDA-approved label and to promote the drugs for off-label

uses. For example, the Actiq label stated that the drug was for opioid-tolerant cancer patients with breakthrough cancer pain, to be prescribed by an oncologist or pain specialist familiar with opioids. Using the mantra, 'Pain is Pain,' Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote this drug for many uses other than breakthrough cancer pain (end of reading).

Do you see that?

A. I see that.

Q. And is that part of the suspicion that you had maybe going on with the sales team and the marketing team?

A. I did not have any suspicion that we were marketing to general practitioners.

Q. Okay. But other than that, that's one element here?

A. That is correct.

Q. Other than that, you had suspicions